



GP 1502  
21/ Suppl  
Prior art Watt  
PATENT

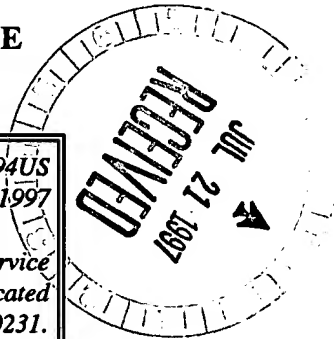
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Express Mail No. EH176731294US  
Date of Deposit July 9, 1997

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231.

A. M. (Andy) Arismendi, Jr.

  
signature of person mailing paper or fee



Be f  
7-28-97

Serial No.: 08/368,378  
Express Mail No.: EH176731294US  
Filed: January 14, 1995  
Examiner: J. Venkat  
Art Unit: 1502  
Applicants: David J. Bova  
Title: NICOTINIC ACID COMPOSITIONS FOR TREATING  
HYPERLIPIDEMIA AND RELATED METHODS THEREFOR

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT ("IDS")**


This Supplemental Information Disclosure Statement is filed pursuant to 37 C.F.R. §§1.97(c) and MPEP 609B(2). Accompanying this filing is a check in an amount of the fee set forth in 37 C.F.R. §§1.17(p) for such a submission (\$230.00). If any additional fees are due, please charge our Deposit Account No. 10-0447.


The disclosures listed on the attached and discussed herein below are called to the attention of the U.S. Patent Office ("PTO") in connection with the above-identified application. A copy of

such disclosures are attached hereto. This Supplemental IDS supplements the IDS filed on April 14, 1995 in connection with the present U.S. patent application, Serial No. 08/368,378.

Information or art known to the Applicant and having any extent of relevance to the present application has been listed on Form PTO-1449 attached hereto. No representation is made that the information or cited disclosures are non-cumulative of the art disclosed, or that the information or cited disclosures represent the only or the best information or disclosures. The Applicant does not admit that any information or cited disclosures he has provided is necessarily prior to his invention, but rather that it is information and disclosures of which he is aware and that he believes should be provided to the PTO in fulfillment of his duty of disclosure. Any question that may arise regarding priority of a specific reference shall be resolved during prosecution. The Examiner is invited to make his/her own independent examination of the information and cited disclosures to determine, in his/her own opinion, their individual or collective materiality as to all pending claims in the above-identified application for U.S. patent.

34. U.S. Patent No. 3,065,143, which issued on November 20, 1962 to Christenson et al. (hereinafter the "Christenson '143 patent"), appears to relate to new dosage units of medicinal agents for oral administration in the form of tablets which provide a substantially constant rate of release of the medicament in the gastrointestinal tract.

35. Not used 

36. Not used. 

37. U.S. Patent No. 4,704,285, which issued on November 3, 1987 to Alderman *et al.* (hereinafter the "Alderman 4,704,285 patent"), appears to relate to sustained release compositions comprising hydroxypropyl cellulose ethers.

38. U.S. Patent No. 4,734,285, which issued March 29, 1988 to Alderman *et al.* (hereinafter the "Alderman 4,734,285 patent"), appears to relate to sustained released compositions employing a fine particle sized hydroxypropyl methylcellulose ether composition.
39. U.S. Patent No. 4,753,801, which issued on June 28, 1988 to Oren *et al.* (hereinafter the "Oren '801 patent"), appears to relate to sustained release tablets in unit dosage form comprising an active agent which has low aqueous solubility.
40. U.S. Patent No. 4,968,508, which was issued on November 6, 1990 to Oren *et al.* (hereinafter the "Oren '508 patent"), appears to relate to a sustained release matrix composition for sustained drug delivery which is comprised of an active agent, a hydrophilic polymer and an enteric polymer.
44. U.S. Patent No. 5,314,697, which issued on May 24, 1994 to Kwan *et al.*, appears to relate to stable extended release oral dosage composition comprising loratadine and pseudoephedrine.
45. U.S. Patent No. 5,286,736, which issued on February 15, 1994 to Soyka *et al.*, appears to relate to pyridyl compounds and pharmaceutical compositions containing these compounds.
46. U.S. Patent No. 5,278,067, which issued on January 11, 1994 to Dawson *et al.*, appears to relate to cyclic ketal derivatives.
47. Not used.
48. U.S. Patent No. 5,264,226, which issued on November 23, 1993 to Graille *et al.*, appears to relate to a process for preparing dairy products with a low content of sterols, particularly of cholesterol.
49. U.S. Patent No. 5,262,435, which issued on November 16, 1993 to Joshua *et al.*, appears to relate to cholesterol lowering compounds.

50. U.S. Patent No. 5,262,165, which issued on November 16, 1993 to Govil et al., appears to relate to transdermal nitroglycerin patch with penetration enhancers.
51. U.S. Patent No. 5,260,305, which issued on November 9, 1993 to Dennick, appears to relate to a combination of Pravastatin and nicotinic acid or related acid and method for lowering serum cholesterol using such combination.
52. U.S. Patent No. 5,258,401, which issued on November 2, 1993 to Berger et al. appears to relate to cholesterol lowering compounds.
53. U.S. Patent No. 5,256,689, which issued on October 26, 1993 to Chiang, appears to relate to cholesterol lowering compounds.
54. U.S. Patent No. 5,213,808, which issued on May 25, 1993 to Bar-Shalom et al., appears to relate to a controlled release article with pulsatile release.
55. U.S. Patent No. 5,211,958, which issued on May 18, 1993 to Akkerboom et al., appears to relate to a pharmaceutical composition and process for its preparation.
56. U.S. Patent No. 5,196,440, which issued on March 23, 1993 to Bertolini et al., appears to relate to compounds active as inhibitors of the cholesterol biosynthesis.
57. U.S. Patent No. 5,190,970, which issued on March 2, 1993 to Pan et al., appears to relate to a method for preventing onset of or treating type II diabetes employing a cholesterol lowering drug alone or in combination with an ace inhibitor.
58. U.S. Patent No. 5,190,940, which issued on March 2, 1993 to Commons et al., appears to relate to cholesterol ester hydrolase inhibitors.
59. U.S. Patent No. 5,188,839, which issued on February 23, 1993 to Pearmain, appears to relate to pharmaceutical compositions of cimetidine.

60. U.S. Patent No. 5,178,854, which issued on January 12, 1993 to Asami et al., appears to relate to cholesterol-lowering agents.
61. U.S. Patent No. 5,182,298, which issued on January 26, 1993 to Helms et al., appears to relate to cholesterol lowering agents.
62. U.S. Patent No. 5,171,570, which issued on December 15, 1992 to Takemori et al., appears to relate to a substance having suppressing function for diseases relating to increase in cholesterol, and foods and drinks in which it is used.
63. U.S. Patent No. 5,169,640, which issued on December 8, 1992 to France et al., appears to relate to pharmaceutical compositions.
64. U.S. Patent No. 5,169,639, which issued on December 8, 1992 to Baichwal et al., appears to relate to controlled release Verapamil tablets.
65. U.S. Patent No. 5,169,638, which issued on December 8, 1992 to Dennis et al., appears to relate to a buoyant controlled release powder formulation.
66. U.S. Patent No. 5,167,964, which issued on December 1, 1992 to Muhammad et al., appears to relate to semi-enteric drug delivery systems and methods for preparing same.
67. U.S. Patent No. 5,145,678, which issued on September 8, 1992 to Gakic et al., appears to relate to a method of reducing blood serum cholesterol.
68. U.S. Patent No. 5,133,974, which issued on July 28, 1992 to Paradissis et al., appears to relate to extended release pharmaceutical formulations.
69. U.S. Patent No. 5,132,116, which issued on July 21, 1992 to Sournac et al., appears to relate to tablets of the hydrophilic matrix type based on Salbutamol and a process for their preparation.
70. U.S. Patent No. 5,130,333, which issued on July 14, 1992 to Pan et al., appears to relate to a method for treating type II diabetes employing a cholesterol lowering drug.

71. U.S. Patent No. 5,128,142, which issued on July 7, 1992 to Mulligan et al., appears to relate to a sustained release drug delivery system.
72. Not used.
73. Not used.
74. Not used.
75. U.S. Patent No. 5,100,675, which issued on March. 31, 1992 to Cho et al., appears to relate to a sustained release tablet comprising loratadine, ibuprofen and pseudoephedrine.
76. U.S. Patent No. 5,047,248, which issued on September 10, 1991 to Calanchi et al., appears to relate to a formulation for preparing sustained release drugs for oral administration.
77. U.S. Patent No. 5,039,341, which issued on August 13, 1991 to Meyer, appears to relate to a binder composition comprises a blend of a high viscosity and low viscosity hydroxypropyl methylcellulose ether, and a tape joint composition containing such binder.
78. Not used.
79. U.S. Patent No. 5,032,406, which issued on July 16, 1991 to Dansereau et al., appears to relate to a dual-action tablet.
80. U.S. Patent No. 5,025,012, which issued on June 18, 1991 to Miura et al., appears to relate to nicotinic acid derivatives and pharmaceutical compositions comprising same.
81. U.S. Patent No. 5,022,774, which issued on June 11, 1991 to Kageyama et al., appears to relate to a writing tool with eraser dispenser.
82. Not used.
83. U.S. Patent No. 5,015,479, which issued on May 14, 1991 to Mulligan et al., appears to relate to a sustained release capsule or tablet formulation- comprising a pharmaceutically acceptable dihydropyridine.

84. U.S. Patent No. 5,009,895, which issued on April 23, 1991 to Lui, appears to relate to sustained release with high and low viscosity HPMC.
85. U.S. Patent No. 4,999,380, which issued on March 12, 1991 to Berger et al., appears to relate to the treatment of lipoprotein disorders associated with cholesterol metabolism.
86. U.S. Patent No. 4,997,658, which issued on March 5, 1991 to Alberts et al., appears to relate to a method for enhancing the lowering of plasma cholesterol levels.
87. U.S. Patent No. 4,996,058, which issued on February 26, 1991 to Sinnreich, appears to relate to covered retard forms.
88. U.S. Patent No. 4,994,276, which issued on February 19, 1991 to Baichwal et al., appears to relate to directly compressible sustained release excipient.
89. U.S. Patent No. 4,992,278, which issued on February 12, 1991 to Khanna, appears to relate to therapeutic system for sparingly soluble active ingredients.
90. U.S. Patent No. 4,990,535, which issued on February 5, 1991 to Cho et al., appears to relate to pharmaceutical composition comprising loratadine, ibuprofen and pseudoephedrine.
91. U.S. Patent No. 4,983,398, which issued on January 8, 1991 to Gaylord et al., appears to relate to sustained release drug dosage forms containing hydroxypropylmethylcellulose and alkali metal carboxylates.
92. U.S. Patent No. 4,973,469, which issued on November 27, 1990 to Mulligan et al., appears to relate to a drug delivery system.
93. U.S. Patent No. 4,970,081, which issued on November 13, 1990 to Frisbee, appears to relate to a controlled-release, low-dose aspirin formulation and method of treating vascular occlusive disease therewith.

94. U.S. Patent No. 4,966,768, which issued on October 30, 1990 to Michelucci et al., appears to relate to a sustained release etodolac.
95. Not used.
96. U.S. Patent No. 4,963,367, which issued on October 16, 1990 to Ecanow, appears to relate to drug delivery compositions and methods.
97. U.S. Patent No. 4,959,478, which issued on September 25, 1990 to Moller et al., appears to relate to a method of producing-coarse crystalline nicotinic acid with a high degree of purity.
98. U.S. Patent No. 4,952,402, which issued on August 28, 1990 to Sparks et al., appears to relate to a controlled release powder and process for its preparation.
99. U.S. Patent No. 4,946,870, which issued on August 7, 1990 to Partain, III. et al., appears to relate to delivery systems for pharmaceutical or therapeutic actives.
100. U.S. Patent No. 4,946,963, which issued on August 7, 1990 to Izydore et al., appears to relate to compounds for the control of hyperlipidemia using n-substituted isoxazolidine-3,5-diones.
101. U.S. Patent No. 4,942,040, which issued on July 17, 1990 to Ragnarsson et al., appears to relate to a pharmaceutical preparation and a process for its preparation.
102. U.S. Patent No. 4,940,588, which issued on July 10, 1990 to Sparks et al., appears to relate to a controlled release powder and process for its preparation.
103. U.S. Patent No. 4,935,246, which issued on June 19, 1990 to Ahrens, appears to relate to a process for the coating of granules.
104. U.S. Patent No. 4,925,905, which issued on May 15, 1990 to Boeckh et al., appears to relate to a preparation of water-soluble copolymers based on monethylenically unsaturated carboxylic acids.
105. Not used.
106. Not used.



107. U.S. Patent No. 4,915,952, which issued on April 10, 1990 to Ayer et al., appears to relate to a composition comprising drug, HPC, HPMC and PEO.
108. Not used.
109. U.S. Patent No. 4,892,741, which issued on January 9, 1990 to Ohm et al., appears to relate to press coated DHP tablets.
110. U.S. Patent No. 4,888,178, which issued on December 19, 1989 to Rotini et al., appears to relate to galenic formulations with programmed release containing naproxen.
111. U.S. Patent No. 4,886,669, which issued on December 12, 1989 to Ventouras, appears to relate to galenical formulation.
112. U.S. Patent No. 4,882,167, which issued on November 21, 1989 to Jang, appears to relate to dry direct compression compositions for controlled release dosage forms.
113. U.S. Patent No. 4,871,548, which issued on October 3, 1989 to Edgren et al., appears to relate to controlled release dosage form comprising different cellulose ethers.
114. U.S. Patent No. 4,866,058, which issued on September 12, 1989 to Izydore et al., appears to relate to a method for control of hyperlipidemia.
115. U.S. Patent No. 4,857,336, which issued on August 15, 1989 to Khanna et al., appears to relate to an oral therapeutic system having systemic action.
116. U.S. Patent No. 4,855,143, which issued on August 8, 1989 to Lowey, appears to relate to a method of preparing controlled long-acting pharmaceutical formulations in unit dosage form having uniform and comparable bioavailability characteristics.
117. U.S. Patent No. 4,851,233, which issued on July 25, 1989 to Khan et al., appears to relate to sustained release formulations.

118. U.S. Patent No. 4,851,232, which issued on July 25, 1989 to Urquhart et al., appears to relate to drug delivery system with means for obtaining desirable in vivo release rate pattern.
119. U.S. Patent No. 4,849,229, which issued on July 18, 1989 to Gaylord et al., appears to relate to controlled release solid drug dosage forms based on mixtures of water soluble nonionic cellulose ethers and anionic surfactants.
120. U.S. Patent No. 4,844,907, which issued on July 4, 1989 to Elger et al., appears to relate to pharmaceutical composition comprising analgesic and anti-inflammatory agent.
121. U.S. Patent No. 4,842,863, which issued on June 27, 1989 to Nishimura et al., appears to relate to granular agent for nunitant and production method thereof.
122. U.S. Patent No. 4,839,177, which issued on June 13, 1989 to Colombo et al., appears to relate to a system for the controlled-rate release of active substances.
123. U.S. Patent No. 4,837,032, which issued on June 6, 1989 to Ortega, appears to relate to a theophylline sustained release tablet.
124. U.S. Patent No. 4,834,965, which issued on May 30, 1989 to Maftani et al., appears to relate to a controlled release pharmaceutical composition.
125. U.S. Patent No. 4,834,985, which issued on May 30, 1989 to Elger et al., appears to relate to a controlled release pharmaceutical composition.
126. U.S. Patent No. 4,830,859, which issued on May 16, 1989 to Finnan et al., appears to relate to a process for lubricating water-soluble vitamin powders.
127. U.S. Patent No. 4,828,836, which issued on May 9, 1989 to Elger et al., appears to relate to a controlled release pharmaceutical composition.
128. U.S. Patent No. 4,824,677, which issued on April 25, 1989 to Shah et al., appears to relate to a grooved tablet for fractional dosing of sustained release medication.

129. U.S. Patent No. 4,824,672, which issued on April 25, 1989 to Day et al., appears to relate to a method and composition for reducing serum cholesterol.
130. U.S. Patent No. 4,814,354, which issued on March 21, 1989 to Ghebre-Sellassie et al., appears to relate to lipid regulating agents.
131. U.S. Patent No. 4,814,183, which issued on March 21, 1989 to Zentner, appears to relate to a device for the controlled release of drugs with donnan-Re modulation by charged insoluble resins.
132. U.S. Patent No. 4,812,316, which issued on March 14, 1989 to Rossi et al., appears to relate to a process for the preparation of stabilized isosorbide-5-mononitrate tablets, being also of sustained release, and formulations thus obtained.
133. U.S. Patent No. 4,803,081, which issued on February 7, 1989 to Falk et al., appears to relate to new pharmaceutical preparations with extended release.
134. U.S. Patent No. 4,803,079, which issued on February 7, 1989 to Hsiao et al., appears to relate to controlled release naproxen and naproxen sodium tablets.
135. U.S. Patent No. 4,795,644, which issued on January 3, 1989 to Zentner, appears to relate to a device for PH independent release of drugs through the donnan-like influence of charged insoluble resins.
136. Not used.
137. U.S. Patent No. 4,795,327, which issued on January 3, 1989 to Gaylord et al., appears to relate to controlled release solid drug dosage forms based on mixtures of water soluble nonionic cellulose ethers and anionic surfactants.
138. U.S. Patent No. 4,713,245, which issued on December 15, 1987 to Ando et al., appears to relate to granule containing physiologically-active substance, method for preparing same and use thereof.

139. U.S. Patent No. 4,710,519, which issued on December 1, 1987 to Finnan et al., appears to relate to a process for preparing spray dried acetaminophen powder and the powder prepared thereby.
140. Not used.
141. Not used.
142. U. S. Patent No. 4,696,762, which issued on September 29, 1987 to Sander et al., appears to relate to hydroxypropylmethylcellulose.
143. U.S. Patent No. 4,695,910, which issued on September 22, 1987 to Maruyama et al., appears to relate to recording disc cartridge having an improved hub assembly.
144. U.S. Patent No. 4,695,467, which issued on September 22, 1987 to Uemura et al., appears to relate to a sustained release tablet.
145. U.S. Patent No. 4,695,591, which issued on September 22, 1987 to Hanna et al., appears to relate to controlled release dosage forms comprising hydroxypropylmethylcellulose.
146. U.S. Patent No. 4,692,337, which issued on September 8, 1987 to Ukigaya et al., appears to relate to a sustained release pharmaceutical tablet of theophylline and production process thereof.
147. U.S. Patent No. 4,690,824, which issued on September 1, 1987 to Powell et al., appears to relate to solid pharmaceutical formulations for slow, zero order release via controlled surface erosion: expanded range.
148. U.S. Patent No. 4,684,516, which issued on August 4, 1987 to Bhutani, appears to relate to sustained release tablets and method of making same.
149. Not used.
150. U.S. Patent No. 4,678,516, which issued on July 7, 1987 to Alderman et al., appears to relate to a sustained release dosage form based on highly plasticized cellulose ether gels.

151. U.S. Patent No. 4,673,405, which issued on June 16, 1987 to Guittard et al., appears to relate to an osmotic system with instant drug availability.
152. U.S. Patent No. 4,657,757, which issued on April 14, 1987 to Hanna et al., appears to relate to a controlled release dosage form comprising acetaminophen, pseudoephedrine sulfate and dextbrompheniramine maleate.
153. U.S. Patent No. 4,794,115, which issued on December 27, 1988 to Takahashi et al., appears to relate to a method of treating hyperlipemia.
154. U.S. Patent No. 4,792,554, which issued on December 20, 1988 to Elben et al., appears to relate to pyridine compounds, pharmaceutical compositions, their use in allergy therapy.
155. U.S. Patent No. 4,792,452, which issued on December 20, 1988 to Howard et al., appears to relate to a controlled release formulation.
156. U.S. Patent No. 4,789,549, which issued on December 6, 1988 to Khan et al., appears to relate to sustained release dosage forms.
157. U.S. Patent No. 4,784,858, which issued on November 15, 1988 to Ventouras, appears to relate to a controlled release tablet.
158. U.S. Patent No. 4,777,042, which issued on October 11, 1988 to Toda et al., appears to relate to cholesterol level-lowering agents.
159. U.S. Patent No. 4,775,535, which issued on October 4, 1988 to Lowey, appears to relate to a method of preparing controlled long-acting pharmaceutical formulations in unit dosage form having uniform and comparable bioavailability characteristics.
160. U.S. Patent No. 4,775,483, which issued on October 4, 1988 to Mookedea et al., appears to relate to a method to reduce plasma cholesterol.

161. U.S. Patent No. 4,764,374, which issued on August 16, 1988 to Grimberg, appears to relate to a pharmaceutical composition based on guar gum and other antacids for protection of the oesogastroduodenal mucous membrane.
162. U.S. Patent No. 4,759,923, which issued on July 26, 1988 to Buntin et al., appears to relate to a process for lowering serum cholesterol- using poly(diallylmethylamine) derivatives.
163. U.S. Patent No. 4,758,581, which issued on July 19, 1988 to Scherm et al., appears to relate to pyridyl N-oxides.
164. Not used.
165. U.S. Patent No. 4,755,544, which issued on July 5, 1988 to Makino et al., appears to relate to a sustained release preparation.
166. U.S. Patent No. 4,753,801, which issued on June 28, 1988 to Oren et al., appears to relate to sustained release tablets.
167. Not used.
168. Not used.
169. U.S. Patent No. 4,747,881, which issued on May 31, 1988 to Shaw et al., appears to relate to an ingestible aggregate and delivery system prepared therefrom.
170. U.S. Patent No. 4,734,285, which issued on March 29, 1988 to Alderman, appears to relate to sustained release compositions.
171. U.S. Patent No. 4,729,895, which issued on March 8, 1988 to Makino et al., appears to relate to a composition for solid pharmaceutical preparations of active vitamins D3 and process for preparation thereof.

172. U.S. Patent No. Re. 32,581, which reissued on January 19, 1988 to Scherm et al., appears to relate to certain substituted phenyl esters of nicotinic acid, compositions and methods of using same for treatment of hyperlipidemia.
173. U.S. Patent No. 4,624,950, which issued on November 25, 1986 to Sasaki et al., appears to relate to a method for treating atherosclerosis hyperlipidema, lipid deposition on arterial walls, or raising the ratio of high density lipoprotein cholesterol to total cholesterol in serum.
174. U.S. Patent No. 4,610,870, which issued on September 9, 1986 to Jain et al., appears to relate to a controlled release formulation.
175. U.S. Patent No. 4,605,666, which issued on August 12, 1986 to Schmidt et al., appears to relate to a process for preparing spray-dried powders containing a water-soluble vitamin and powders prepared thereby.
176. U.S. Patent No. 4,603,142, which issued on July 29, 1986 to Burger et al., appears to relate to a cholesterol lowering method of use.
177. U.S. Patent No. 4,576,604, which issued on March 18, 1986 to Guittard et al., appears to relate to an osmotic system with instant drug availability.
178. U.S. Patent No. 4,571,333, which issued on February 18, 1986 to Hsiao et al., appears to relate to a controlled release naproxen and naproxen sodium tablets.
179. Not used.
180. U.S. Patent No. 4,556,678, which issued on December 3, 1985 to Hsiao, appears to relate to a sustained release propranolol tablet.
181. Reexamination Certificate No. B1 4,389,393, which issued on October 22, 1985 to Schoret al., appears to relate to sustained release therapeutic compositions based on high molecular weight hydroxypropylmethylcellulose.

182. U.S. Patent No.: 4,547,359, which issued on October 15, 1985 to Zierenberg et al., appears to relate to a divisible pharmaceutical tablet with delayed active ingredient release.
183. U.S. Patent No. 4,540,566, which issued on September 10, 1985 to Davis et al., appears to relate to prolonged release drug dosage forms based on modified low viscosity grade hydroxypropylmethacrylate.
184. U.S. Patent No. 4,539,198, which issued on September 3, 1985 to Powell et al., appears to relate to solid pharmaceutical formulations for slow, zero order release via controlled surface erosion: expanded range.
185. U.S. Patent No. 4,525,345, which issued on June 25, 1985 to Dunn et al., appears to relate to constant order release, solid dosage indomethacin formulation and method of treating arthritis and other inflammatory conditions.
186. U.S. Patent No. 4,522,804, which issued on June 11, 1985 to Dunn, appears to relate to constant release rate solid oral dosage formulations of propranolol.
187. U.S. Patent No. 4,485,105, which issued on November 27, 1984 to Shepherd, appears to relate to a method of treating hyperlipidemia with 4-(monoalkylamino)benzoic acid amides.
188. U.S. Patent No. 4,478,819, which issued on October 23, 1984 to Hercelin et al., appears to relate to novel oral preparations.
189. U.S. Patent No. 4,472,436, which issued on September 18, 1984 to Hooper, appears to relate to increasing HDL-cholesterol levels with phenylethylamine derivatives.
190. U.S. Patent No. 4,465,660, which issued on August 14, 1984 to David et al., appears to relate to a sustained release tablet containing at least 95 percent theophylline.
191. U.S. Patent No. 4,461,759, which issued on July 24, 1984 to Dunn, appears to relate to constant release rate solid oral dosage formulations of veropamil.



192. U.S. Patent No. 4,457,907, which issued on July 3, 1984 to Porter, appears to relate to a composition and method for protecting a therapeutic drug.
193. U.S. Patent No. 4,455,298, which issued on June 19, 1984 to McFarlane et al., appears to relate to pharmaceutical preparations with gastro-protective action.
194. U.S. Patent No. 4,454,108, which issued on June 12, 1984 to Iida et al., appears to relate to prolonged-action multiple-layer tablets.
195. U.S. Patent No. 4,452,775, which issued on June 5, 1984 to Kent, appears to relate to a cholesterol matrix delivery system for sustained release of macro molecules.
196. U.S. Patent No. 4,440,940, which issued on April 3, 1984 to Shepherd, appears to relate to anti-atherosclerotic agents.
197. U.S. Patent No. 4,428,951, which issued on January 31, 1984 to Hata et al., appears to relate to a long acting pharmaceutical composition.
198. U.S. Patent No. 4,382,143, which issued on May 3, 1983 to Shepherd, appear to relate to hypolipidemic and antiatherosclerotic novel (monosubstituted-amino) heteroaryl carboxylic acids and analogs.
199. U.S. Patent No. 4,375,468, which issued March 1, 1983 to Dunn, appears to relate to constant order release aspirin composition and method of treating arthritis.
200. U.S. Patent No. 4,367,217, which issued January 4, 1983 to Gruber et al., appears to relate to dipyricamole sustained release forms comprising lacquer-coated particles and the preparation thereof.
201. U.S. Patent No. 4,362,711, which issued on December 7, 1982 to Cerami, appears to relate to blood cholesterol level reducing agent and method.

202. U.S. Patent No. 4,361,546, which issued on November 30, 1982 to Stricker et al., appears to relate to a retard form of pharmaceuticals with insoluble porous diffusion coatings.
203. U.S. Patent No. 4,357,469, which issued on November 2, 1982 to Schor, appears to relate to a carrier base material for prolonged release therapeutic compositions.
204. U.S. Patent No. 4,353,887, which issued on October 12, 1982 to Hess et al., appears to relate to a divisible tablet having controlled and delayed release of the active substance.
205. U.S. Patent No. 4,348,399, which issued on September 7, 1982 to Shepherd, appears to relate to antiatherosclerotic and hypolipidemic 4-(monoalkylamino)phenyl alkane, alkene and alkyne carbinols, aldehydes, carboxylic acids and derivatives.
206. U.S. Patent No. 4,326,525, which issued on April 27, 1982 to Swanson et al., appears to relate to an osmotic device that improves delivery properties of agent in situ.
207. U.S. Patent No. 4,318,914, which issued on March 9, 1982 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic 4-(polyfluoro-alkylamino)phenyl compounds.
208. U.S. Patent No. 4,310,545, which issued on January 12, 1982 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic 4-(polyfluoroalkylamino) phenyl compounds.
209. U.S. Patent No. 4,309,404, which issued on January 5, 1982 to-DeNeale et al., appears to relate to sustained release pharmaceutical compositions.
210. U.S. Patent No. 4,308,251, which issued on December 29, 1981 to Dunn et al., appears to relate to controlled release formulations of orally-active medicaments.
211. U.S. Patent No. 4,305,959, which issued on December 15, 1981 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic 4-(polyfluoro-alkylamino)phenyl compounds).
212. U.S. Patent No. 4,291,030, which issued on September 22, 1981 to Mulinos, appears to relate to a method of lowering blood cholesterol.

213. U.S. Patent No. 4,285,951, which issued on August 25, 1981 to Hoefle, appears to relate to 2,2-dimethyl-5-(2,5-dimethylphenoxy)pentyl ester of 3-pyridine carboxylic acid and use as an anti-atherosclerotic agent.
214. U.S. Patent No. 4,283,382, which issued on August 11, 1981 to Frank et al., appears to relate to fluorescent labels comprising rare earth chelates.
215. U.S. Patent No. 4,282,233, which issued on August 4, 1981 to Vilani, appears to relate to antihistamic 11-(4-piperidylidene)-5H-benzo-[5,6]-cyclohepta-[1,2-B]-pyridines.
216. U.S. Patent No. 4,279,898, which issued on July 21, 1981 to Engel et al., appears to relate to in vivo inhibitors of cholesterol biosynthesis.
217. U.S. Patent No. 4,272,548, which issued on June 9, 1981 to Gatzen et al., appears to relate to a process for the lowering of increased levels of cholesterol and neutral fat in the blood of humans.
218. U.S. Patent No. 4,268,524, which issued on May 19, 1981 to Cavazza, appears to relate to a method of treating abnormal lipoprotein ratios with acylcamitine.
219. U.S. Patent No. 4,261,970, which issued on April 14, 1981 to Ogawa et al., appears to relate to theophylline sustained release granule.
220. U.S. Patent No. 4,259,314, which issued on March 31, 1981 to Lowey, appears to relate to a method and composition for the preparation of controlled long-acting pharmaceuticals.
221. U.S. Patent No. 4,256,108, which issued on March 17, 1981 to Theeuwes, appears to relate to microporous-semipermeable laminated osmotic system.
222. U.S., Patent No. 4,255,449, which issued on March 10, 1981 to Cavazza, appears to relate to a method of treating abnormal lipoprote in ratios.

223. U.S. Patent No. 4,251,519, which issued on February 17, 1981 to Robbins et al., appears to relate to a process for the prevention and reduction of elevated blood cholesterol and triglycerides levels.
224. U.S. Patent No. 4,248,857, which issued on February 3, 1981 to DeNeale et al., appears to relate to sustained release pharmaceutical compositions.
225. U.S. Patent No. 4,237,118, which issued on December 2, 1980 to Howard, appears to relate to dietary supplement and dietary methods employing said supplement for the treatment of obesity.
226. U.S. Patent No. 4,230,878, which issued on October 28, 1980 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic 4-[(cyclopropyl alkyl)amino]benzoic acids and derivatives.
227. U.S. Patent No. 4,226,849, which issued on October 7, 1980 to Schor, appears to relate to sustained release therapeutic compositions.
228. U.S. Patent No. 4,211,783, which issued July 8, 1980 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic novel 4-(aralkyl-and heteroarylalkylamino)phenyl compounds.
229. U.S. Patent No. 4,205,085, which issued on May 27, 1980 to Shepherd, appears to relate to hypolipidemic and antiatherosclerotic 4-(polyfluoroalkylamino)phenyl compounds.
230. U.S. Patent No. 4,203,439, which issued May 20, 1980 to Theeuwes, appears to relate to an osmotic system with volume amplifier for increasing amount of agent delivered therefrom.
231. U.S. Patent No. 4,182,902, which issued on January 8, 1980 to Thiele et al., appears to relate to novel cholesterol-lowering compounds.
232. U.S. Patent No. 4,180,064, which issued on December 25, 1979 to Heller et al., appears to relate to a system for delivering agent to environment of use over prolonged time.
233. U.S. Patent No. 4,178,387, which issued on December 11, 1979 to Diamond et al., appears to relate to a method for the treatment of arrhythmia.

234. U.S. Patent No. 4,169,944, which issued October 2, 1979 to Scallen et al., appears to relate to cholesterol biosynthesis inhibitors.
235. U.S. Patent No. 4,167,558, which issued on September 11, 1979 to Sheth et al., appears to relate to novel sustained release tablet formulations.
236. Not used.
237. U.S. Patent No. 4,160,452, which issued on July 10, 1979 to Theeuwes, appears to relate to an osmotic system having laminated wall comprising semipermeable lamina and microporous lamina.
238. U.S. Patent No. 4,160,020, which issued on July 3, 1979 to Ayer et al., appears to relate to a therapeutic device for osmotically dosing at controlled rate.
239. U.S. Patent No. 4,140,755, which issued on February 20, 1979 to Sheth et al., appears to relate to sustained release tablet formulations.
240. U.S. Patent No. 4,126,672, which issued on November 21, 1978 to Sheth et al., appears to relate to sustained release pharmaceutical capsules.
241. U.S. Patent No. 4,117,111, which issued on September 26, 1978 to Fields et al., appears to relate to a method for lowering blood cholesterol level.
242. U.S. Patent No. 4,116,241, which issued on September 26, 1978 to Theeuwes et al., appears to relate to an osmotic system with laminated wall comprising structurally different semipermeable lamina.
243. U.S. Patent No. 4,115,550, which issued on September 19, 1978 to Fields et al., appears to relate to a composition for lowering blood cholesterol level.
244. U.S. Patent No. 4,102,806, which issued on July 25, 1978 to Kondo et al., appears to relate to a method of producing micro capsules and resulting product.

245. U.S. Patent No. Re. 29,652, which reissued on May 30, 1978 to Fields et al., appears to relate to a method of lowering blood cholesterol level.
246. U.S. Patent No. 4,077,407, which issued on March 7, 1978 to Theeuwes et al., appears to relate to osmotic devices having composite walls.
247. U.S. Patent No. 4,067,876, which issued on January 10, 1978 to Ferruti et al., appears to relate to high polymers containing nicotinic acid, process for their preparation and their use.
248. U.S. Patent No. 4,058,122, which issued on November 15, 1977 to Theeuwes et al., appears to relate to an osmotic system with laminated wall formed of different materials.
249. U.S. Patent No. 4,034,758, which issued on July 12, 1977 to Theeuwes, appears to relate to an osmotic therapeutic system for administering medicament.
250. U.S. Patent No. 4,034,087, issued on July 5, 1977 to Voorhees appears to relate to a pharmaceutical composition and process of treatment.
251. U.S. Patent No. 4,014,987, which issued on March 29, 1977 to Heller et al., appears to relate to a device for delivery of useful agent.
252. U.S. Patent No. 4,014,334, which issued on March 29, 1977 to Theeuwes et al., appears to relate to a laminated osmotic system for dispensing beneficial agent.
253. U.S. Patent No. 4,011,339, issued on March 8, 1977 to Galantay et al., appears to relate to hypolipidemic allene carboxylic acids.
254. U.S. Patent No. 4,008,719, which issued on February 22, 1977 to Theeuwes et al., appears to relate to an osmotic system having laminar arrangement for programming delivery of active agent.
255. U.S. Patent No. 4,002,641, which issued on January 11, 1977 to Moller et al., appears to relate to pyrazole derivatives.

256. U.S. Patent No. 3,992,536, which issued on November 16, 1976 to Kleemann et al., appears to relate to pharmaceutical compositions containing a 1-phenyl-2,2,2,4,4-C,-C2 alkyl-3-[4(phenyl or pyridyl)-piperazinol-cyclobutanol-(I) and method of use.
257. U.S. Patent No. 3,987,160, which issued on October 19, 1976 to Broughton et al., appears to relate to pharmaceutical compositions comprising azapurinones useful in treating allergic respiratory disorders.
258. U.S. Patent No. 3,977,404, which issued on August 31, 1976 to Theeuwes, appears to relate to an osmotic device having microporous reservoir.
259. U.S. Patent No. 3,965,255, which issued on June 22, 1976 to Bloch et al., appears to relate to controlled drug releasing preparations.
260. U.S. Patent No. 3,959,492, which issued on May 25, 1976 to Coulston et al., appears to relate to a method for reducing serum blood cholesterol.
261. U.S. Patent No. 3,957,976, which issued on May 18, 1976 to Sugimoto, appears to relate to methods for reducing cholesterol levels.
262. U. S. Patent No. 3,951,821, which issued on April 20, 1976 to Davidson, appears to relate to a disintegrating agent for tablets.
263. U.S. Patent No. 3,930,017, which issued on December 30, 1975 to Kummer et al., appears to relate to lowering blood cholesterol and lipid levels.
264. U.S. Patent No. 3,924,001, which issued on December 2, 1975 to Albright et al., appears to relate to hypolipidemic 4-(monoalkylamino) benzoic acid derivatives.
265. U.S. Patent No. 3,923,972, which issued on December 2, 1975 to Fields et al., appears to relate to a method of lowering blood cholesterol level.

266. U.S. Patent No. 3,870,790, which issued on March 11, 1975 to Lowey et al., appears to relate to solid pharmaceutical formulations containing hydroxypropyl methyl cellulose.
267. U.S. Patent No. 3,868,416, which issued on February 25, 1975 to Albright et al., appears to relate to hypolipidemic 4-(monoalkylamino) benzoic acid derivatives.
268. U.S. Patent No. 3,862,332, which issued on January 21, 1975 to Barnhart et al., appears to relate to a method of lowering serum cholesterol.
269. U.S. Patent No. 3,859,437, which issued on January 7, 1975 to Weigand, appears to relate to reducing cholesterol levels.
270. U.S. Patent No. 3,849,554, which issued on November 19, 1974 to Winitz, appears to relate to a reduction of blood serum cholesterol.
271. U.S. Patent No. 3,806,601, which issued on April 23, 1974 to Mikite et al., appears to relate to a cholesterol and lipid-lowering therapeutical agent.
272. U.S. Patent No. 3,795,691, which issued on March 5, 1974 to Douglas et al., appears to relate to cholesterol-lowering agents.
273. U.S. Patent No. 3,773,920, which issued on November 20, 1973 to Nakamoto et al., appears to relate to sustained release medicinal composition.
274. U.S. Patent No. 3,721,735, which issued on March 20, 1973 to Thiffault, appears to relate to compositions for and method of lowering cholesterol levels.
275. U.S. Patent No. 3,709,991, which issued on January 9, 1973 to Miller, appears to relate to a hypolipidemic method.
276. U.S. Patent No. 3,639,636, which issued on February 1, 1972 to Barnhart, appears to relate to a method of lowering serum cholesterol.



277. U.S. Patent No. 3,634,584, which issued on January 11, 1972 to Poole, appears to relate to a sustained action dosage form.
278. U.S. Patent No. 3,629,453, which issued on December 21, 1971 to Waring, appears to relate to compositions and methods for reducing serum cholesterol and esterified fatty acids.
279. U.S. Patent No. 3,629,393, which issued on December 21, 1971 to Nakamoto, et al., appears to relate to a release-sustaining tablet.
280. U.S. Patent No. 3,626,071, which issued on December 7, 1971 to Kariya, et al., appears to relate to compositions and methods for reducing cholesterol in the blood.
281. U.S. Patent No. 3,590,117, which issued on June 29, 1971 to Christenson, et al., appears to relate to a long-lasting troche containing guar gum.
282. U.S. Patent No. 3,495,011, which issued on February 10, 1970 to Fossel, appears to relate to a reduction of blood level cholesterol.
283. U.S. Patent No. 3,424,842, which issued on January 28, 1969 to Nurnberg, appears to relate to the manufacture of tablets directly from dry powders.
284. U.S. Patent No. 3,336,200, which issued on August 15, 1967 to Krause et al., appears to relate to tablet structure.
285. U.S. Patent No. 3,272,832, which issued on September 13, 1966 to Nakano et al., appears to relate to nicotinic acid derivatives and process for the preparation thereof.
286. U.S. Patent No. 3,210,413, which issued on October 5, 1965 to Blank et al., appears to relate to antihypercholesterolemic agents.
287. U.S. Patent No. 3,193,461, which issued on July 6, 1965 to Elsen, appears to relate to correcting blood changes with niacin, vitamin A, and riboflavin.

288. U.S. Patent No. 3,147,187, which issued on September 1, 1964 to Playfair, appears to relate to sustained release pharmaceutical.
289. U.S. Patent No. 3,143,469, which issued on August 4, 1964 to Debay, et al., appears to relate to anti-cholesterol nicotinic acid N-oxide.
290. U.S. Patent No. 3,134,719, which issued on May 26, 1964 to Sheth, et al., appears to relate to calcium phosphates in tablet compressing.
291. U.S. Patent No. 3,116,204, which issued on December 31, 1963 to Siegel, et al., appears to relate to pharmaceutical compositions and method of preparing the same.
292. U.S. Patent No. 3,108,046, which issued on October 22, 1963 to Harbit, appears to relate to method of preparing high dosage sustained release tablet and product of this method.
293. U.S. Patent No. 3,062,720, which issued on November 6, 1962 to Costello, appears to relate to sustained release pharmaceutical tablet.
294. U.S. Patent No. 2,957,804, which issued on October 25, 1960 to Shuyler, appears to relate to pesticide.
295. U.S. Patent No. 2,887,436, which issued on May 19, 1959 to Klioze, et al., appears to relate to pharmaceutical compositions.
296. U.S. Patent No. 2,857,313, which issued on October 21, 1958 to Cooper et al., appears to relate to self-lubricating granulation.
297. U. S. Patent No. 2,851,453, which issued on September 9, 1958 to Kennon, et al., appears to relate to cellulose derivative product, compositions comprising the-same and their preparation.
298. U.S. Patent No. 2,805,977, which issued on September 10, 1957 to Robinson et al., appears to relate to sustained release pharmaceutical preparation.

299. U.S. Patent No. 2,798,838, which issued on July 9, 1957 to Robinson, appears to relate to method of preparing acetophenetidin tablets.
300. U.S. Patent No. 2,798,837, which issued on July 9, 1957 to Sahyun, appears to relate to achlorhydria composition.
301. U.S. Patent No. 2,749,274, which issued on June 5, 1956 to Buckwalter, appears to relate to stable aqueous procaine penicillin suspension.
302. U.S. Patent No. 2,540,979, which issued on February 6, 1951 to Clymer, et al., appears to relate to enteric coating.
303. U.S. Patent No. 2,510,164, which issued on June 6, 1950 to Woodward, et al., appears to relate to water-insoluble derivatives of nicotinic acid and process. for preparing them.
304. Canadian Patent No. 603,690, which issued on Aug. 16, 1960 to Hamada, appears to relate to a quinidine glucomate sustained medication tablet.
305. French Patent No. 1,302,362, which issued on July 23, 1962, appears to relate to a prolonged-release tablet composition.
306. Japanese, Patent Abstract, No. 40-2053, which is dated Feb. 1965, appears to relate to durable granules and tablets.
307. Japanese Patent Abstract No. 46-18151, which is dated May 1971, appears to relate to a delayed release medicament preparation.
308. Japanese Patent Abstract, No. 0049312, which is dated April 1980, appears to relate to preparing slow release pharmaceutical-by coating granules containing active component with wax, water-sol. high mol. cpd. and nonionic surfactant and tableting.
309. PCT Publication No. WO 84/00104, which was published on January 19, 1984, appears to relate to a sustained release propranolol tablet.

310. EPO Patent Abstract, No. 0109320, which is dated May 23, 1984, appears to relate to a controlled-release theophylline tablets - with hydrophilic matrix based on hydroxy-propyl methylcellulose.

311. EPO Patent Application No. 0126453, which is dated November 28, 1984, appears to relate to a controlled release pharmaceutical tablet - is compressed with slant end punch to provide sloping face and compression gradient.

312. United Kingdom Patent Application No. 2 141 338 A, which was published on Dec. 19, 1984, appears to relate to controlled release naproxen and naproxen sodium tablets.

313. United Kingdom Patent Application No. 2 154 874 A, which was published on Sept. 18, 1985, appears to relate to bromocriptine compositions.

314. Not used.

AAA. Krycer I et al: *Powder Technology*, 34:39-51 (1983) appears to relate to the evaluation of tablet binding agents such as solution binders.

AAB. 19\_\_ Dow Chemical Company publication is entitled "Technical Information: Methods of Formulating Controlled Release Products Outside the Forest Lab Patent U.S. 4,389,393 Claims."

AAC. 1982 Dow Chemical Company publication is entitled "Formulating Sustained Release Pharmaceutical Products with Methocel."

AAD. 1987 Dow Chemical Company publication is entitled "Formulating for Controlled Release with Methocel cellulose Ethers."

AAE. 1989 Regulatory Letter, Department of Health & Human Services, addressed to Nutritional Products, Inc. (February 21, 1989) appears to relate to Nia-trol 500 mg caplets.

AAF. Luria M H: *Arch. Intern. Med.*, 148:2493-2495 (1988) appears to relate to the effect of low-dose niacin on high-density lipoprotein cholesterol and total cholesterol/high-density lipoprotein ratio.

AAG. Kruse W et al: *Eur. J. Clin. Pharmacol.*, 16:11-15 (1979) appears to relate to the nocturnal inhibition of lipolysis in man by nicotinic acid and derivatives.

AAH. Altschul R: *Arch. Biochem. Biophys*, 54:448-559 (1955) appears to relate to the influence of nicotinic acid on serum cholesterol in man.

AAI. Carlson L A et al: *Acta Med. Scand.*, 183:457-465 (1968) appears to relate to the effect of a single dose of nicotinic acid on plasma lipids in patients with hyperlipoproteinemia.

AAJ. Neuvonen P J et al: *Br. J. Clin. Pharmac.*, 32:473-476 (1991) appears to relate to the bioavailability of sustained release nicotinic acid formulations.

AAK. Keenan J M et al: *JAGS*, 40:12-18 (1992) appears to relate to the treatment of hypercholesterolemia wherein a comparison of younger versus older patients using wax-matrix sustained-release niacin was made.

AAL. Cayen M N et al: *Artherosclerosis*, 45(3):281-290 (December, 1982) appears to relate to the effect of AY-25,712 [2-methyl-2-phenyl-3(2H)-furanone-5-carboxylic acid] and nicotinic acid on various aspects of free fatty acid (FFA) and trygliceride metabolism in male rats.

AAM. Subissi A et al: *J. Pharm. Pharmacol.*, 35(9):571-575 (September, 1983) appears to relate to the acute affects on plasma lipids in the rat of a new long-acting nicotinic acid derivative: LG 13979.

AAN. Criscuoli M et al: *Artherosclerosis*, 53(1):59-68 (1984) appears to relate to glunicate (LG 13979) which protects the arterial wall from cholesterol-induced atheosclerotic changes in a rabbit without affecting plasma lipids.

AAO. Renzetti A R et al: *J. Pharm Pharmacol.*, 37(12):906-909 (December, 1985) appears to relate to the assessment of glunicate hypolipidaemic activity in rats.

AAP. Miettinen T A: *Annals of Clinical Research*, 12:295-298 (1980) appears to relate to the diurnal variation of LDL and HDL cholesterol.

AAQ. Miettinen T A: *Metabolism*, 34(5):425-430 (May, 1985) appears to relate to cholesterol precursors in their diurnal rhythm and lipoproteins of patients with jejuno-ileal bypass and ileal disfunction.

AAR. Miettinen T A: *J. Lipid Research*, 23:466-473 (1982) appears to relate to the diurnal variation of cholesterol precursors squalene in methyl sterols in human plasma lipoproteins.

AAS. Letter, *JAMA*, 264(2):181 (July 11, 1990) appears to relate to acute hepatic failure associated with the use of low-dose sustain-release niacin.

AAT. Schlierf G et al: *Artery*, 3(2):174-179 (1977) appears to relate to the inhibition of carbohydrate induced hypertriglyceridemia by nicotinic acid.

AAU. Schlierf G et al: *J. Clin. Invest.*, 52(3):732-740 (March, 1973) appears to relate to diurnal patterns of triglycerides, free fatty acids, blood sugar, and insulin during carbohydrate-induction in man and their modification by nocturnal suppression of lipolysis.

AAV. 1971 Abstract, Schlierf G et al: *Pharmacological Control of Lipid Metabolism, Proceedings of the Fourth International Symposium on Drugs Affecting Lipid Metabolism, Philadelphia, PA*, 26:319-320 (September, 1971) appears to relate to the modification of carbohydrate-induced triglyceridemia by nocturnal suppression of lipolysis and the comparison of nicotinic acid and glucose.

AAW. Hunninghake D B: *Upsher-Smith Laboratories, Inc.* publication (1990) appears to relate to issues in cholesterol management and a reappraisal of niacin.

AAX. 1988 Slow-Niacin® Advertisement, *American Druggist*, 141-142 (April, 1988) appears to relate to an advertisement for Slow-Niacin®.

AAY. 1988 Regulatory Letter addressed to Upsher-Smith Laboratories, and dated June 6, 1988 appears to relate to Slow-Niacin® 250 mg., 500 mg. and 750 mg.

AAZ. 1989 Dow Chemical Company publication is entitled "Formulating for Controlled Release with Methocel cellulose Ethers" appears to relate to the use of hydroxypropylmethylcellulose (Methocel) as a controlled release agent.

AB. Jacobson T A et al: *The American Journal of Cardiology*, 73:25D-29D (May. 26, 1994) appears to relate to combination therapy with fluvastatin and niacin in hypercholesterolemia and further concerns a preliminary report on safety.

AC. Squires R W et al: *Mayo Clin. Proc.*, 67:855-860 (1992) appears to relate to low- dose, time-release nicotinic acid and its effects in selected patients with low concentrations of high-density lipoprotein cholesterol.

AD. Rader J I et al: *The American Journal of Medicine*, 92:77-81 (January, 1992) appears to relate to hepatic toxicity of unmodified and time-release preparations of niacin.

AE. Keenan J M: *JAMA Specialty Journal Abstracts*, 266(16):2209 (1991) appears to relate to a randomized controlled trial of wax-matrix sustained-release niacin in hypercholesterolemia.

AF. Keenan J M et al: *Arch. Intern. Med.*, 151:1424-1432 (July 1991) appears to relate to a randomized, controlled trial of wax-matrix sustained-release niacin in hypercholesterolemia.

AG. Henkin Y et al: *JAMA*, 264(2):241-243 (1990) appears to relate to rechallenge with crystalline niacin after drug-induced hepatitis from sustained-release niacin.

AH. Handbook of Nonprescription Drugs, Nutritional Supplements, 9th Edition, American Pharmaceutical Association, 470-471 (1990) appears to relate to niacin (nicotinic acid).

- AI. Schulman K A et al: JAMA, 264(23):3025-3033 (December 19, 1990) appears to relate to reducing high blood cholesterol level with drugs.
- AJ. Brown G et al: The New England Journal of Medicine, 323(19):1289-1298 (November 8, 1990) appears to relate to regression of coronary artery disease as a result of intensive lipid-lowering therapy in men with high levels of apolipoprotein B.
- AK. Alderman J D et al: Am. J. Cardiol., 64(12):725-729 (October 1, 1989) appears to relate to the effect of a modified, well-tolerated niacin regimen on serum total cholesterol, high density lipoproteiri, cholesterol and the cholesterol to high density lipoprotein ratio.
- AL. Carlson L A et al: J. Internal Medicine, 226:271-76 (1989) appears to relate to pronounced lowering of serum levels of lipoprotein Lp(a) in hyperlipidaemic subjects treated with nicotinic acid.
- AM. Blum C B et al: JAMA, 261(24):3582-3587 (1989) appears to relate to current therapy for hypercholesterolemia.
- AN. 1989 Dow Chemical Company publication which appears to relate to formulating for controlled release with Methocel premium cellulose ethers.
- AO. Kowalski R. E.: The 8-Week Cholesterol Cure, Harper & Row, Publishers, 95-115 and notes 345-346 (1989) appears to relate to a story of niacin.
- AP. Manninen M et al: JAMA, 260(5):641-651 (1988) appears to relate to lipid alterations and decline in the incidence of coronary heart disease in the Helsinki heart study.
- AQ. Figge H L et al: J. Clin. Pharmacol., 28:1136-1140 (1988) appears to relate to a comparison of excretion of nicotinuric acid after ingestion of two controlled release nicotinic acid preparations in man.
- AR. Figge H L et al: Pharmacotherapy, 8(5):287-294 (1988) appears to relate to nicotinic acid and a review of its clinical use in the treatment of lipid disorders.



- AS. Urberg M et al: The Journal of Family Practice, 27(6):603-606 (1988) appears to relate to hypocholesterolemic effects of nicotinic acid and chromium supplementation.
- AT. Wahlberg G et al: Acta. Med. Scand., 224:319-327 (1988) appears to relate to the effects of nicotinic acid on concentrations of serum apolipoproteins B, C-1, C-II, C-RI and E in hyperlipidemic patients.
- AU. Chain Drug Review Publication, page 12, June 6, 1988, P. Leiner, which appears to relate to a time release niacin product under its Your Life brand.
- AV. Cooper K H: Bantam Books, Dr. Kenneth H. Cooper's Preventive Medicine Program, Controlling Cholesterol, 244-253 (1988) which appears to relate to the wisdom and risk of drug and vitamin therapy.
- AW. Urberg M et al: Metabolism, 36(9):896-899 (September, 1987) appears to relate to the evidence for synergism between chromium and nicotinic acid in the control of glucose tolerance in elderly humans.
- AX. Blankenhorn D H et al: JAMA, 257(23):159-166 (June 19, 1987) appears to relate to the beneficial effects of combined colestipol-niacin therapy on coronary atherosclerosis and coronary venous bypass grafts.
- AY. Canner P L et al: JACC, 8(6):1245-1255 (December, 1986) appears to relate to fifteen year mortality in coronary drug project patients and long-term benefit with niacin.
- AZ. Sokoloski T D: Solutions and Phase Equilibria, in Remington's 17th Edition Pharmaceutical Sciences, Mack Publishing Company, 207-208 (1985) appears to relate to solutions and solubility.
- BA. Dow Chemical Company publication, 1-15 (1985) appears to relate to methocel as a binding agent for tablet production by wet granulation.

- BC. The Merck Index, Merck & Co. Inc., Tenth Edition, 809,520,351,466 (1983) appears to relate to morpholine sulfate, pseudoephedrine, codeine sulfate and diltiazem.
- BD. Korsmeyer R W et al: Journal of Pharmaceutical Sciences, 72(10):1189,1191 (October, 1983) appears to relate to mechanisms of potassium chloride release from compressed, hydrophilic, polymeric matrices and the effect of entrapped air.
- BE. Malkowska S et al: Drug Development and Industrial Pharmacy, Marcel Dekker, Inc., 9(3):349-361 (1983) appears to relate to the effect of re-compression on the properties of tablets prepared by moist granulation.
- BF. Davis S S et al: Modern Concepts in Nitrate Delivery Systems, 29-37, edited by A.A.J. Goldberg and D.G. Parsons, 1983: Royal Society of Medicine International Congress and Symposium Series No. 54, published jointly by Academic Press Inc. (London) Ltd., and the Royal Society of Medicine, appears to relate to scintigraphic studies on the in vivo dissolution of a buccal tablet.
- BG. Kane J P et al: The New England Journal of Medicine, 304(5):251-258 (Jan. 29, 1981) appears to relate to the normalization of low-density-lipoprotein levels in heterozygous familial hypercholesterolemia with a combined drug regimen.
- BH. Chowhan Z T et al: Journal of Pharmaceutical Sciences, 70(10):1134-1139 (October, 1981) appears to relate to the compression properties of granulations made with binders containing different moisture contents.
- BI. Cayen M N: Drug Metabolism Reviews, 11(2):291-323 (1980) appears to relate to the metabolic disposition of antihyperlipidemic agents in man and laboratory animals.
- BJ. Rowland M et al: Clinical Pharmacokinetics: Concepts and Applications publication, Lea & Febiger, 111 (1980) appears to relate to a zero-order process.

BK. Chowhan Z T: Journal of Pharmaceutical Sciences, 69(1):1-3 (January, 1980) appears to relate to the role of binders in moisture-induced hardness increase in compressed tablets and its effect on in vitro disintegration and dissolution.

BL. Gudsoorkar, V R et al: Indian Drugs & Pharmaceuticals Industry, 3-4 (July-August, 1980) appears to relate to the influence of binders on some physical parameters of lactose and sulfadimidine tablets.

BM. Ibrahim, S A et al: Pharmazie, 35(8):567 (1980) appears to relate to the release characteristics of oxyphenbutazone from different suppository bases.

BN. Pintye-Hodi K et al: Phannazier, 35(3):168-170 (1980) appears to relate to the Untersuchungen uber die Textur und die Eigenschaften von Acetylsalicylsdure-Tabletten.

BO. Buriat P et al: Pharm. ACTA Helv., 33(7-8):189-197 (1980) appears to relate to the formulation des comprimés à libération prolongée.

BP. Shepherd J et al: J. Clin. Invest., 63:858-867 (May, 1979) appears to relate to the effects of nicotinic acid therapy on plasma high density lipoprotein subtraction distribution and composition and on apolipoprotein A metabolism.

BQ. Salomon J L et al: Pharm. ACTA Helv., 54(3):82-85 (1979) appears to relate to the importance de la technologic et de la formulation pour le mécanisme de libération du chlorure de potassium contenu dans des matrices hydrophiles.

BR. Salomon J L et al: Pharm. ACTA Helv., 54(3):75-85 (1979) appears to relate to the importance of technique and formulation on the release mechanism of potassium chloride contained in hydrophilic matrices.

BS. Salomon J L et al: Pharm. Ind., 41(8):799-802 (1979) appears to relate to the sustained release of a water-soluble drug from hydrophilic compressed dosage forms.

BT. Abumrad N A et al: Journal of Lipid Research, 19:423-432 (1978) appears to relate to the studies on serum lipids, insulin, and glucagon and on muscle triglyceride in rats adapted to high-fat and high-carbohydrate diets.

BU. Chowhan T et al: Journal of Pharmaceutical Sciences, 67(10):1385-1389 (October, 1978) appears to relate to the hardness increase induced by partial moisture loss in compressed tablets and its effect on in vitro dissolution.

BV. Keresztes N A et al: Pharmazie, 33(11):747-749 (1978) appears to relate to Untersuchungen über die Textur und die Eigenschaften von Acetylsalicylsäure-Tabletten.

BW. The Coronary Project Research Group: JAMA, 231(4):36-381 (Jan. 27, 1975) appears to relate to clofibrate and niacin in coronary heart disease.

BX. Laguna O et al: Annales Pharmaceutiques Françaises, 33(5):235-242 (1975) appears to relate to Influence de quelques produits filmogènes et plastifiants sur la dissolution de comprimés à base de chlorure de sodium.

BY. Fleischman A I et al: Fed. Proc. 34(1), 248 (1975) appears to relate to low dose sustained release nicotinic acid as an effective hypolipidemic agent in man.

BZ. Remington's Pharmaceutical Sciences, 1576-1587 (1975) appears to relate to tablets, capsules and pills.

CA. Remington's Pharmaceutical Sciences, 1242-1251 (1975) appears to relate to emulsifying and suspending agents.

CB. Schlierf G et al: Nutr. Metabol., 13:80-91 (1971) appears to relate to the diurnal patterns of plasma triglycerides and free fatty acids in normal subjects and in patients with endogenous (type IV) hyperlipoproteinemia.

- CC. Barter P J et al: The Journal of Clinical Investigation, 50:583-591 (1971) appears to relate to the diurnal fluctuations in triglyceride, free fatty acids, and insulin during sucrose consumption and insulin infusion in man.
- CD. Miettinen T A: Annals of Clinical Research, 2:300-320 (1970) appears to relate to the detection of changes in human cholesterol metabolism.
- CE. Ekström-Jodal, B et al: Pharmacologia Clinica, 2:86-89 (1970) appears to relate to the influence of nicotinic acid and pentaerythritoltetranicotinate on the cardiac output in man.
- CF. Lapidus H et al: Journal of Pharmaceutical Sciences, 57(8):1292-1301 (August 1968) appears to relate to drug release from compressed hydrophilic matrices.
- CG. Carlson L A et al: Acta Med Scand, 183(5):457-465 (May 1968) appears to relate to the effect of a single dose of nicotinic acid on plasma lipids in patients with hyperlipoproteinemia.
- CH. Lapidus H et al: Journal of Pharmaceutical Sciences, 57(8):1292-1301 (August 1968) appears to relate to drug release from compressed hydrophilic matrices.
- CI. Carlson L A et al: The Journal of Clinical Investigation, 47:1795-1805 (1968) appears to relate to plasma lipids and urinary excretion of catecholamines in man during experimentally induced emotional stress, and their modification by nicotinic acid.
- CJ. Carlson L A: Progr. Biochem. Pharmacol., 3:151-166 (1967) appears to relate to the consequences of inhibition of normal and excessive lipid mobilization.
- CK. Pinter E. J. et al: Preliminary Communications, 27:440-443 (March 1967) appears to relate to the biphasic nature of blood glucose and free fatty acid changes following intravenous nicotinic acid in man.
- CL. Lapidus H: University Microfilms International, Thesis, Rutgers University, 1-117 (1983) appears to relate to drug release from compressed hydrophilic matrices.

CM. Lapidus H et al: Journal of Pharmaceutical Sciences, 55(8):840-843 (August 1966) appears to relate to some factors affecting the release of a water-soluble drug from a compressed hydrophilic matrix.

CN. Huber H E et al: Journal of Pharmaceutical Sciences, 55:974-976 (September 1966) appears to relate to the utilization of hydrophilic gums for the control of drug release from tablet formulations

#### I. Disintegration and Dissolution Behavior.

CO. Carlson L A: Clinica Chimica Acta, 13:349-350 (1966) appears to relate to the determination of free nicotinic acid in blood plasma.

CP. Carlson L A et al: Acta Medica Scandinavica, 179:453-461 (fasc. 4, 1966) appears to relate to acute effects of nicotinic acid in the rat.

CQ. Altschul R et al: Charles C. Thomas, 42-135 (1964) appears to relate to niacin in vascular disorders and hyperlipemia.

CR. Mahl M: The American Journal of the Medical Sciences, 64:673-677 (December, 1963) appears to relate to a long term study of the effect of nicotinic acid medication on hypercholesteremia.

CS. Carlson L A: Acta Medica Scandinavica, 173:719-722 (fasc. 6, 1963) appears to relate to studies on the effect of nicotinic acid on catecholamine stimulated lipolysis in adipose tissue in vitro.

CT. Carlson L A et al: Acta Medica Scandinavica, 172:641-645 (fasc. 6, 1962) appears to relate to the effect of nicotinic acid on the plasma free fatty acids.

CU. Berge K G et al: American Journal of Medicine, 31:24-35 (July 1961) appears to relate to hypercholesteremia and nicotinic acid.

CV. Christensen N A et al: J.A.M.A., 177(8):76-80 (August 26, 1961) appears to relate to nicotinic acid treatment of hypercholesteremia.

CW. Altschul R et al: Academic Press Inc., 51:308-309 (1954) appears to relate to the influence of oxygen inhalation on cholesterol metabolism.

CX. Miller O N et al: American Journal of Clinical Nutrition, 8:480-490 (July-August 1960) appears to relate to the investigation of the mechanism of action of nicotinic acid on serum lipid levels in man.

CY. Carlson L A; Annals New York Academy of Sciences, III(471):118-143 (1985) appears to relate to inhibition of the mobilization of free fatty acids from adipose tissue.

CZ. Dow Chemical: Appears to relate to product designation changes for methocel cellulose ethers.

DA. Kassem A A et al: Department of Pharmaceuticals, Faculty of Pharmacy, Cairo University, 275-306. Appears to relate to enhancement of release rate of spironolactone from its tablets by the formation of solid dispersions with water-soluble polymers.

DB. Lapidus H: Chemistry, 2363-B-2364-B (1967) appears to relate to drug release from compressed hydrophilic matrices.

DC. Dow Chemical: Handbook on Methocel\* Cellulose Ether Products, appears to relate to the molecular weight-viscosity relationship.

DD. Svedmyr N: Clinical Pharmacology and Therapeutics, 559-570 appears to relate to the relationship between the plasma concentration of free nicotinic acid and some of its pharmacologic effects in man.

DE. Alderman J D et al: Clinical Research, Abstract 1883, IIII-471 (October 1985) appears to relate to major favorable changes in cholesterol and HDL in coronary patients using a modified niacin regimen.

DF. Carlson, L A: Annals New York Academy of Sciences, 119-142 (19\_\_ ) appears to relate to inhibition of the mobilization of free fatty acids from adipose tissue.

DG. Dow Chemical: (19\_\_ ) appears to relate to product designation changes for methocel cellulose ethers.

DH. Kassem A A et al: Jami at Al-Qahira, Faculty of Pharmacy, Bulletin, Cairo, 19(1):275-306 (1980) appears to relate to enhancement of release rate of spironolactare from its tablets by the formation of solid dispersions with water-soluble polymers.

DI. Lapidus H: Chemistry, Abstract, (order no. 67-14, 728) 2363-B-2364-B (1967) appears to relate to drug release from compressed hydrophilic matrices.

DJ. Dow Chemical Company Publication: (1974) appears to relate to a handbook on methocel cellulose ether products.

DK. SvedmyrN et al: Clinical Pharmacology and Therapeutics, 10(4):559-570 (19\_\_ ) appears to relate to the relationship between the plasma concentration of free nicotinic acid and some of its pharmacologic effects in man.

Respectfully submitted,

Jenkins & Gilchrist, P.C.

By Peter J. Manso  
Peter J. Manso  
Reg. No. 32,264

1445 Ross Avenue  
Suite 3200  
Dallas, Texas 75202-2799  
(713) 951-3375

Am. (Am) Arisimendi, Jr  
REG. 31,715